DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

HFI-35

9152

One Montvale Avenue
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(781) 279-1675
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February 01, 2001

WARNING LETTER

NWE–13–01W

VIA FEDERAL EXPRESS

Lawrence C. Brooks, DVM
Powder Ridge Veterinary Hospital
375 Route 147
Middlefield, CT 06455

Dear Dr. Brooks:

An investigation at your veterinary practice located in Middlefield, CT (Powder Ridge Veterinary Hospital, 375 Route 147) was conducted by Investigator John Hollings on December 18, 2001. That investigation was initiated in response to a United States Department of Agriculture (USDA) report regarding an illegal gentamicin residue in a cow offered for sale and slaughter for human food by [redacted] in [redacted], CT. The investigation revealed that you prescribed and dispensed [redacted] brand of Gentamicin Sulfate Solution (Veterinary) for the treatment of this cow. Food containing illegal drug residues is adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigation also revealed that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

In November 2000, [redacted] sold (traded) a dairy cow identified by farm tag [redacted] and back tag [redacted], for slaughter as human food to [redacted], a livestock dealer in [redacted], CT. This animal was shipped to the [redacted] Packing Co., [redacted], PA where it was slaughtered. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the animal's kidney at a level of 4.74 ppm. Gentamicin has not been approved for use in cattle. There is no established tolerance for residues of gentamicin in the edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated under Section

402(a)(2)(C)(ii) of the Act.

The gentamicin used by [redacted] to treat this cow is adulterated under Section 501(a)(5) in that it is a new animal drug that is unsafe within the meaning of Section 512 of the Act. Section 512 deems, in part, that a new animal drug is unsafe unless an FDA approved application is in effect and the drug, its labeling, and use conform to such an approved application or the implementing regulations for *Extralabel Drug Use in Animals*, Title 21, Code of Federal Regulations, Part 530.

The Animal Medicinal Drug Use and Clarification Act (AMDUCA) passed by Congress in October 1994 and the implementing regulations[1] that became effective December 9, 1996, permit the extralabel use of approved human and veterinary drugs in food-producing animals only under very specific criteria.

The investigation at your facility revealed that you prescribed and dispensed a 100 ml bottle of [redacted] (100 mg/ml Gentamicin Sulfate) for treatment of mastitis in a cow. Gentamicin is not approved for this use. Under certain conditions, a veterinarian may consider extralabel use when the health of the animal is immediately threatened and suffering or death would result from failure to treat the affected animal.

You did not meet these conditions. Extralabel use must be by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian / client / patient relationship and that use may not result in any residue above its tolerance. There is no tolerance for gentamicin in the edible tissue of cattle. The decision to use a drug in an extralabel manner may not be made by a layperson.

When you prescribe and dispense animal drugs for extralabel use in the treatment of disease conditions in food-producing animals, you assume added responsibility. You must establish a substantially extended withholding period supported by appropriate scientific information; you must assure the identity of a treated animal is carefully maintained; and you must take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal residues occur. This includes assuring that your client will follow your instructions.

This letter is not intended to be an all-inclusive list of violations at your facility. It is therefore incumbent upon you to take added precautions such as providing to all producers and animal handlers detailed written and verbal instructions and cautions explaining the potential consequences of failing to follow your instructions. You should also limit the quantity of drug provided, institute a method of animal identification to ensure treated animals are readily identified as such, and follow up with your clients to ensure the instructions regarding the use of the drug and prescribed withdrawal times are followed.

[1] Title 21, Code of Federal Regulations, Part 530 (21 CFR Part 530). A copy of these regulations has been enclosed for your reference. Or visit www.access.gpo.gov/nara/cfr/waisidx_00/21cfr530_00.html

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as injunction and/or prosecution.

You should notify this office in writing within fifteen (15) working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections been made.

Your reply should be directed to Mark Lookabaugh, Compliance Officer at the address noted above. If you have any questions concerning this matter, please contact Mr. Lookabaugh at ***781.279.1675 x1718***,

Sincerely,

Gail T. Costello
Director
New England District Office

Enclosure